

REMARKS

This amendment is in response to the Office Action dated January 20, 2010. No claims have been amended, no claims have been canceled, and no claims have been added; as such, claims 1-8 are now pending in this application. Claims 1, 4 and 7-12 are independent claims. Reconsideration and allowance is requested in view of the following remarks.

I. 35 USC § 102/103 Rejections : Claim 5

Claim 5 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Gropper et al (US 5,540,220, hereinafter referred to as "Gropper '220") or in the alternative under 35 U.S.C. § 103 (a). Applicant respectfully traverses this rejection.

Claim 5 recites:

An oxygen supplying apparatus comprising

an oxygen generating means,

an oxygen supplying means for supplying the oxygen generated by the oxygen generating means to a user and

a single automatic closing valve placed on an oxygen-supplying passage, wherein the oxygen supplying apparatus comprising:

a respiration sensor which detects the respiration of the user and provides a respiration signal;

a supply method setting means which selects the supply in a continuous flow or the oxygen supply in synchronism with the respiration of the user;

a flow rate setting means for setting a supply flow rate set value; and

a controlling means which controls an aperture of said single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means by receiving a supply method setting signal of the continuous flow, or opens said

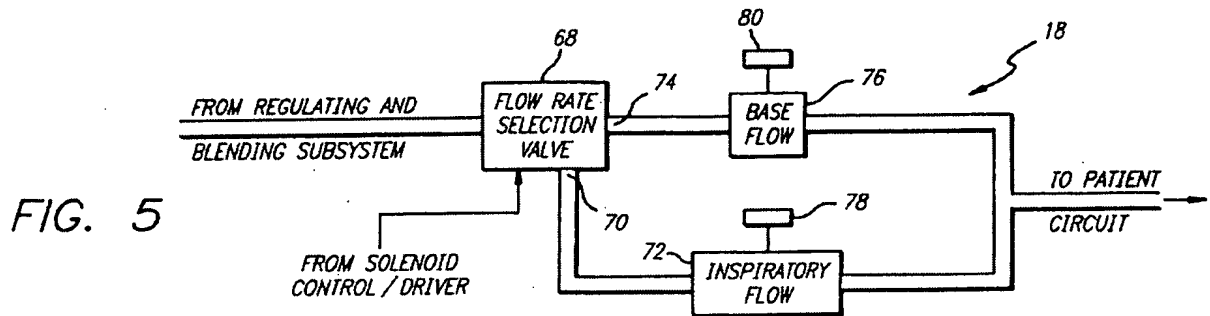
single automatic closing valve on the inhalation starting point based on the respiration signal of the respiration sensor by receiving a supply method setting signal of the synchronous flow and at the same time controls the open time of said single automatic closing valve corresponding to the flow rate set value, wherein the supply method setting means and the flow rate setting means are composed separately and independently.

The Office Action, however, alleges these feature can be found in various sections of Gropper '220. This is wholly inaccurate.

Gropper '220 relates to a method and apparatus for pulmonary ventilation support which represents an improvement in the mode of mechanical ventilation known as "pressure-limited, time-cycled" ventilation (col. 1, ll. 8-13). The pressure-limited, time-cycled pulmonary ventilator of Gropper '220 includes a pressurized gas system that supplies respiratory gas to a patient at a selected inspiratory flow rate; an exhalation valve that (a) opens an expiratory flow path in response to the elapsing of a selected inspiratory time period, and (b) maintains a selected proximal pressure limit during the inspiratory time period; and a volume-cycle override system that actuates the exhalation valve so as to open the expiratory flow path if the patient's tidal volume reaches or exceeds a selected volume limit during the inspiratory time period.

Column 8, lines 37 – 55, of Gropper '220 illustrates the components and function of the flow control subsystem 18 (see FIG. 5 reproduced below). Gas from the regulating and blending subsystem 16 is received in the inlet of a solenoid-actuated flow rate selection valve 68. The flow rate selection valve 68 has two outlets: a first outlet 70 communicates with the inlet of a clinician-adjustable inspiratory flow valve 72, and a second outlet 74 communicates with the inlet of a clinician-adjustable base flow valve 76. Either the first or second outlet of the flow rate selection valve 68 is opened in response to a first solenoid actuation signal generated by the solenoid control/driver circuit 66. The first solenoid actuation signal actuates the flow rate selection valve 68 so as to open its first outlet during inspiratory phase and its second outlet during expiratory phase. In other words, Gropper '220 discloses **three valves**, namely, **a clinician-adjusted inspiratory**

flow valve 72 and a clinician-adjusted base flow valve 76 in addition to flow rate selection valve 68.



Foremost, as discussed in the previous response to the Non-Final Office Action dated August 4, 2009, Gropper '220 fails to disclose, teach or suggest **a single automatic closing valve** placed on an oxygen-supplying passage which is controlled by the controlling means based on the selection by the oxygen supply method setting means as to whether the selection is the oxygen supply in a continuous flow or the oxygen supply in synchronism with the respiration of the user. Indeed, Gropper '220 discloses **three valves**, namely, a flow rate selection valve 68, a clinician-adjustable inspiratory flow valve 72 and a clinician-adjustable base flow valve 76, placed on an oxygen-supplying passage. The flow rate selection valve 68 operates to which select which of the two inlets 70 and 74, the flow rate is adjusted by the valves 72, 76 respectively (col. 8, ll. 38-56). The flow rate selection valve 68 does not select the modes of the oxygen supply in a continuous flow or the oxygen supply in synchronism with the respiration of the user.

The Office Action states that the fact that another valve is used in addition to the flow rate valve in Gropper '220 to arrive at the desired flow rate does not patentably distinguish the invention because there is no limitation in the claims that the single closing valve operates alone to arrive at the final desired flow rate. This is improper reading of claim 5.

Applicant's claim 5 explicitly claims "an oxygen supplying means for supplying the oxygen generated by the oxygen generating means to a user and **a single automatic closing valve** placed on an oxygen-supplying passage, wherein the oxygen supplying apparatus comprising," and

“a controlling means which controls an aperture of said single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means.” Clearly, the **single closing valve** operates alone to arrive at the final desired flow rate. In contrast, Gropper ‘220 discloses **three valves**, namely, a flow rate selection valve 68, a clinician-adjustable inspiratory flow valve 72 and a clinician-adjustable base flow valve 76, placed on an oxygen-supplying passage to control the flow rate.

Moreover, the Office Action alleges that the single automatic closing valve is only in the preamble of the claim. Again this is an improper reading of claim 5. The claim recites “[a]n oxygen supplying apparatus comprising,” and then recites a single automatic closing valve. The first mention of “comprising” delineates the end of the preamble and the beginning of the claim features.

Furthermore, Gropper ‘220 **fails** to disclose, teach or suggest *“a respiration sensor which detects the respiration of the user and provides a respiration signal.”* The Office Action alleges that flow rates of inspiration and expiration can in fact be read on detecting the respiration of the user and providing a respiration signal. Again this is inaccurate.

Again as discussed in the previous response to the Non-Final Office Action dated August 4, 2009, Gropper ‘220 discloses flow sensor 40 and flow sensor circuit 42. The flow sensor 40 generates an analog output signal indicative of instantaneous flow rate of gas inhaled and exhaled by the patient being processed and conditioned by a flow sensor circuit 42 (col. 7, ll. 40-45). The flow sensor 40 does **NOT** detect respiration of the user. Rather the flow sensor 40 detects flow rate of gas through the patient connector 24. Further, the flow sensor circuit 42 **ONLY** produces a digitized **inhalation flow rate** signal and outputs to a CPU (col. 7, ll. 54-57, col. 16, ll. 13-14, col. 16, ll. 62-64). Thus, Gropper ‘220 **fails** to disclose, teach or suggest *“a respiration sensor which detects the respiration of the user and provides a respiration signal.”* The signal of which includes a signal for both **inhalation and exhalation**.

Moreover, Gropper ‘220 **fails** to disclose, teach or suggest *“a supply method setting means which selects the supply in a continuous flow or the oxygen supply in synchronism with the respiration of the user.”* In particular, since, as stated above, Gropper ‘220 **fails** to disclose, teach

or suggest "the supply in a continuous flow." Rather, Gropper '220 discloses limited supply of gas flow **without continuous flow**. Since Gropper '220 **fails** to disclose, teach or suggest a respiration sensor which detects the respiration of the user, Gropper '220 **fails** to disclose, teach or suggest the supply in synchronism with the respiration of the user. To the contrary, the "**exhalation**" of the user is "**impeded**" (see col. 15, l. 9) by the Gropper '220 device.

Finally, Gropper '220 **fails** to disclose, teach or suggest "*a controlling means which controls an aperture of said single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means by receiving a supply method setting signal of the continuous flow, or opens said single automatic closing valve on the inhalation starting point based on the respiration signal of the respiration sensor by receiving a supply method setting signal of the synchronous flow and at the same time controls the open time of said single automatic closing valve corresponding to the flow rate set value, wherein the supply method setting means and the flow rate setting means are composed separately and independently.*"

The Office Action, however, alleges these feature can be found in col. 17, lines 33-36 of Gropper '220. This is wholly inaccurate.

As stated above, Gropper '220 relates to a method and apparatus for pulmonary ventilation support which represents an improvement in the mode of mechanical ventilation known as "pressure-limited, time-cycled" ventilation.

Col. 17, lines 33-36 of Gropper '220 state:

If the ventilator is not in the assist disabled period, the algorithm next determines if the assist trigger "window" is open; that is, if the ventilator's operational mode would, at that point in the breath cycle, permit the ventilator to provide a machine-assisted breath. If the "window" is open, the assist trigger module 98 generates an assist trigger output signal that is inputted to the breath control module 56. The breath control module 56, in turn, responds by sending a control signal having the first (inspiration initiation) value to the solenoid control driver circuit 66, which, in turn, responds by generating the first and second solenoid actuation signals having their respective first values, as described above. As a result, as also described above, the first and second solenoid actuation signals actuate the flow rate selection valve 74 to select the inspiratory flow rate, and the

reference pressure selection valve 94 to select the PIP reference pressure.
The result of these actuations is to cause the ventilator to deliver a machine-assisted breath to the patient.

In other words, column 17; lines 5 – 31, of Gropper '220 discloses the controlling valves dependent on "assist disabled" period. It is stated that if the ventilator is not in the assist disabled period, an algorithm determines if the assist trigger "window" is open; that is, if the ventilator's operational mode would permit the ventilator to provide machine-assisted breath, that, if the window is open, the assist trigger module 98 of Fig. 4 generates an assist trigger output signal that is inputted to the breath control module 56, that the breath control module 56, in turn, responds by sending a control signal having the first (inspiration initiation) value to the solenoid control driver circuit 66, which, in turn, responds by generating first and second solenoid actuation signals, and that, as a result, the first and second solenoid actuation signals actuate the flow rate selection valve [68] to select the inspiratory flow rate, and the reference pressure selection valve 94 [of pressure reference subsystem 36 (see Fig. 6)] to select the PIP reference pressure.

Clearly, there is **no mention** of controlling an aperture of said single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means by receiving a supply method setting signal of the continuous flow, **or** opens said single automatic closing valve on the inhalation starting point based on the respiration signal of the respiration sensor by receiving a supply method setting signal of the synchronous flow **and** at the same time controls the open time of said single automatic closing valve corresponding to the flow rate set value in Gropper '220.

- **Therefore Gropper '220 fails to disclose, teach or suggest a controlling means which controls an aperture of said single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means by receiving a supply method setting signal of the continuous flow, or opens said single automatic closing valve on the inhalation starting point based on the respiration signal of the respiration sensor by receiving a supply method setting signal of the synchronous flow and at the same time controls the open time of said single automatic closing valve corresponding to the flow**

rate set value, wherein the supply method setting means and the flow rate setting means are composed separately and independently.

As such, Gropper '220 fails to teach or suggest various features of independent claim 1. For reasons similar to those regarding claim 5.

Accordingly, Applicant respectfully requests that the rejection of the claim 5 under 35 U.S.C. § 102(b) as being anticipated by Gropper '220 be withdrawn and under 35 U.S.C. § 103(a) as being unpatentable over Gropper '220 be withdrawn.

II. 35 USC § 103 Rejections : Claims 6 and 7

Claims 6 and 7 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Gropper '220 in view of the admitted prior art. Applicant respectfully traverses this rejection.

Claims 6 and 7 depend from and thus incorporate the features of claim 5, which is neither disclosed nor suggested by Gropper '220, for the reasons stated above.

The admitted prior art does not remedy the deficiencies of Gropper '220, as the various features recited above are also absent from the admitted prior art. For example, Applicant's claimed features of "*a controlling means which controls an aperture of said single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means by receiving a supply method setting signal of the continuous flow, or opens said single automatic closing valve on the inhalation starting point based on the respiration signal of the respiration sensor by receiving a supply method setting signal of the synchronous flow and at the same time controls the open time of said single automatic closing valve corresponding to the flow rate set value, wherein said single automatic closing valve is controlled by the controlling means which had taken the information set by the supply method setting means and the flow rate setting means,*" are neither disclosed nor suggested by the admitted prior art.

Accordingly, Applicant respectfully requests that the rejection of claims 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over Gropper '220 in view of the admitted prior art be withdrawn.

III. 35 USC § 103 Rejection : Claim 8

Claim 8 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Gropper '220.

Claim 8 depends from and thus incorporates the features of claim 5, which is neither disclosed nor suggested by Gropper '220, for the reasons stated above.

Accordingly, Applicant respectfully requests that the rejection of claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Gropper '220.

IV. Double Patenting Rejection

Claims 1-8 have been provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of co-pending Application No. 10/569,463. Applicant traverses this rejection.

The Office Action admits that the conflicting claims are not identical (page 5, last paragraph), and explains that the instant claim 1 does not include the structural element of the exhaust means or pressure measuring means as in the co-pending claim 8. The Office Action further states that the structural elements [of claim 1] are included in the co-pending claim 8. This is totally inaccurate.

Claim 8 of the co-pending application is dependent from claim 5, which is dependent from claim 3, which is dependent from claim 1. Thus claim 8 include all the limitations of claims 1, 3 and 5.

Applicant notes that claim 1 of the co-pending Application No. 10/569,463 states:

An oxygen concentration apparatus comprising:

pressure swing adsorption type oxygen concentration means including: ***at least one adsorption column*** formed of a cylinder hollow having first and second ports, an inside of said cylinder hollow is filled with an adsorbent selectively adsorbing nitrogen rather than oxygen; ***pressurized air supply means*** connected with the ***first port of said adsorption column*** and supplying pressurized air to said adsorption column; ***exhaust means*** connected with the first port of said adsorption column and allowing exhaust from said adsorption column; and ***switching means*** allowing said ***pressurized air supply means*** and said ***exhaust means*** to communicate with said ***first port selectively***, said pressure swing adsorption type oxygen concentration means generates oxygen concentrated gas by repeating an adsorption process in which said ***pressurized air supply means*** supplies pressurized air to said adsorption column to adsorb the nitrogen from said air, and a regeneration process in which said ***exhaust means*** depressurizes said adsorption column to separate the nitrogen adsorbed by said adsorption column to regenerate said adsorbent;

a conduit communicating at its one end with the second port of said oxygen concentration means and introducing the oxygen concentrated gas generated by said oxygen concentration means from said second port into a user; and

flow rate adjusting means provided in said conduit and adjusting a flow rate of the oxygen concentrated gas generated by said oxygen concentration means,

said oxygen concentration apparatus further comprises:

pressure measuring means disposed between said oxygen concentration means and said flow rate adjusting means in said conduit; and

control means controlling at least the switching means of said oxygen concentration means and said flow rate adjusting means,

wherein said control means adjusts a cycle of the adsorption and regeneration processes of said oxygen concentration means and controls pressure at the upstream

of said flow rate adjusting means by controlling said switching means based on pressure of said oxygen concentrated gas in said conduit measured by said pressure measuring means.

Clearly, this is completely different than claim 1 of Applicant's invention which states:

An oxygen supplying apparatus comprising an oxygen generating means, an oxygen supplying means for supplying the oxygen generated by the oxygen generating means to a user and a single automatic closing valve placed on an oxygen-supplying passage, wherein the oxygen supplying apparatus comprising:

a respiration sensor which detects the respiration of the user and provides a respiration signal;

a supply method setting means which selects the supply in a continuous flow or the supply in synchronism with the respiration of the user;

a flow rate setting means for setting a supply flow rate set value; and,

a controlling means which controls an aperture of said single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means by receiving a supply method setting signal of the continuous flow, or opens said single automatic closing valve on the inhalation starting point based on the respiration signal of the respiration sensor by receiving a supply method setting signal of the synchronous flow and at the same time controls the open time of said single automatic closing valve corresponding to the flow rate set value, wherein said single automatic closing valve is controlled by the controlling means which had taken the information set by the supply method setting means and the flow rate setting means.

Accordingly, Applicant requests withdrawal of the double patenting rejection.

MPEP §804II.B. states as follows:

A double patenting rejection of the obviousness-type, if not based on an anticipation rationale, is "**analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103**" except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, the analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Since the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis. These factual inquiries are summarized as follows:

- (A) Determine the scope and content of a patent claim relative to a claim in the application at issue;
- (B) Determine the differences between the scope and content of the patent claim as determined in (A) and the claim in the application at issue;
- (C) Determine the level of ordinary skill in the pertinent art; and
- (D) Evaluate any objective indicia of nonobviousness.

The conclusion of obviousness-type double patenting is made in light of these factual determinations.

Any obviousness-type double patenting rejection should make clear:

(A) The differences between the inventions defined by the conflicting claims - a claim in the patent compared to a claim in the application; and

(B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue is anticipated by, or would have been an obvious variation of, the invention defined in a claim in the patent. (Emphasis added.)

It is respectfully submitted that the Office Action has not established the reasons why a person of ordinary skill in the art would conclude that the invention defined in claim 1 of this application is anticipated by, or would have been an obvious variation of, the invention in the co-pending application claim 8.

Further, MPEP§2141 III states as follows:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396. (Emphasis added.)

The Office Action has not established clearly “articulated reasoning with rational underpinning to support the legal conclusion of obviousness [of double patenting].”

V. Conclusion

In view of the above amendment and remarks, applicant believes the pending application is in condition for allowance.

This response is believed to be a complete response to the Office Action. However, Applicant reserves the right to set forth further arguments supporting the patentability of their claims, including the separate patentability of the dependent claims not explicitly addressed herein, in future papers. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicant expressly does not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

VI. Extensions of time

Please treat any concurrent or future reply, requiring a petition for an extension of time under 37 C.F.R. §1.136, as incorporating a petition for extension of time for the appropriate length of time.

The Commissioner is hereby authorized to charge all required fees, fees under 37 C.F.R. §1.17, or all required extension of time fees.

Application No. 10/524,632
Amendment dated April 14, 2010
After Final Office Action of January 20, 2010

Docket No.: TEI-0131

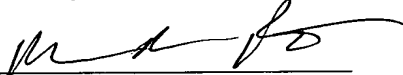
VII. Fees-general authorization

The Commissioner is hereby authorized to charge any deficiency in fees filed, asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm).

If any fee is required or any overpayment made, the Commissioner is hereby authorized to charge the fee or credit the overpayment to Deposit Account # 18-0013.

Dated: April 14, 2010

Respectfully submitted,

By 

Maulin M. Patel

Registration No.: 56,029

RADER, FISHMAN & GRAUER PLLC

Correspondence Customer Number: 23353

Attorney for Applicant